II. REMARKS

Preliminary Remarks

Reconsideration and allowance of the present application based on the following remarks are respectfully requested. Claims 1-3, 5, 6, and 13-32 are currently pending in the application. Claims 1 and 30-32 have been cancelled without prejudice because these claims were withdrawn from further consideration as allegedly being drawn to a non-elected invention, and not for any reason related to patentability. Claims 17, 19, 20, 27, and 29 have been allowed. Claims 2, 3, 5, 6, 13-16, 18, 21-26, and 28 remain at issue.

On page 3 of the official action, the examiner alleged the recently submitted declaration was defective under 37 C.F.R. § 1.67(a) because the residence listed for inventor Andreas Tauch was incorrectly spelled as "Blefeld." The applicants hereby submit a newly executed oath with the correctly spelling of Andreas Tauch's address.

The specification on page 5, line 25-30 has been amended to recite the address of the biological deposit DSM5816. "A Declaration of Biological Deposit in Compliance with the Budapest Treaty" accompanies "Amendment B."

The applicants have amended claim 2 to be directed to a plasmid capable of autonomous replication in bacteria of the genus Corynebacterium, said plasmid comprising (i) at least one region that encodes a protein involved in a biosynthetic pathway selected from the group consisting of L-lysine and pantothenic acid; (ii) at least one DNA replication region obtained from one of the plasmids pTET3 or pCRY4, and (iii) at least one region that encodes a protein for active antibiotic resistance comprising a gene selected from the group consisting of a gene encoding a protein conferring tetracycline resistance, a gene encoding a protein conferring streptomycin and spectinomycin resistance, and a gene conferring sulfamethoxazole resistance, wherein said genes are obtained from the antibiotic resistance region of plasmid pTET3, as set forth in Figure 5. Support parts (i) and (iii) of amended claim 2 can be found throughout the specification, for example, on page 30, lines 14-33, page 13, line 29 to page 14, line 7, Examples 11 and 12, and figure 5.

The applicants have amended claim 6 to be directed to a plasmid capable of autonomous replication in bacteria of the genus Corynebacterium containing at least one DNA replication region obtained from one of the plasmids pGA1, pGA2, pTET3, or pCRY4,

and at least one region encodes for a protein for active antibiotic resistance comprising a gene selected from the group consisting of a gene encoding a protein conferring tetracycline resistance, a gene encoding a protein conferring streptomycin and spectinomycin resistance, and a gene conferring sulfamethoxazole resistance, wherein said genes are obtained from the antibiotic resistance region of plasmid pTET3, as set forth in Figure 5. Support for part (ii) of amended claim 6 can be found throughout the specification, for example, on page 30, lines 14-33 and figure 5.

Claim 22 has been amended to be directed to the plasmid of claim 21, wherein said plasmid is compatible with one or more plasmids selected from the group consisting of pGA1, pGA2, pAG3, pBL1, and pHM1519. Support for amended claim 6 can be found throughout the specification for example, on page 2, lines 25-30; page 5, lines 25-30, and page 14, lines 12-24.

Claim 25 has been amended to be directed to the plasmid of claim 24, wherein said plasmid is compatible with one or more plasmids selected from the group consisting of pGA1, pGA2, pAG3, pBL1, and pHM1519. These amendments clarify which plasmids are compatible with pCRY4, and are not for any reason of patentability. Support for amended claim 25 can be found throughout the specification, for example, on page 14, line 25 to page 15, line 7.

New claim 33 is directed to the plasmid of claim 2, wherein the region encoding a protein involved in a biosynthetic pathway consists of a lysC gene of *C. glutamicum* encoding an aspartate kinase and a panD gene of *C. glutamicum* encoding an aspartate α-decarboxylase. Support for new claim 33 can be found throughout the specification, for example, from page 13, line 29 to page 14, line 7 and Examples 11 and 12.

The applicants do not intend by these or any amendments to abandon subject matter of the claims as originally filed or later presented, and reserve the right to pursue such subject matter in continuing applications.

Patentability Remarks

Rejection Pursuant to 35 U.S.C. § 112, Second Paragraph, Indefiniteness

On page 4 of the official action, the examiner rejected claims 2, 3, 5, 13, 15, 16, 22, 26, and 28 under 35 U.S.C. § 112, second paragraph, as assertedly containing indefinite terminology.

The examiner alleged that claim 2 and its' dependent claims 3, 5, 13, and 15 were indefinite because the recitation "active antibiotic resistance" is unclear. Specifically, the examiner asserted it is unclear how "active" antibiotic resistance is different from "antibiotic resistance" and what the term "active" adds to the claim. The applicants have cancelled claims 3, 5, and 13 without prejudice, thereby obviating the rejection of these claims. As discussed above, claim 2 has removed the term "active" in front of the phrase "antibiotic resistance," as suggested by the examiner, for which the applicants are grateful.

The examiner further rejected claim 16 under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite in the recitation of "constituents of plasmid pTET3." The applicants have amended claim 16 to be directed to the plasmid of claim 6 wherein said plasmid consists of the DNA replication region obtained from pTET3 and at least one antibiotic resistance gene obtained from the antibiotic resistance gene region of plasmid pTET3, as set for in Figure 5. The applicants submit that claim 6 is now clearly directed to a plasmid with particular regions, i.e. a replication and antibiotic region from pTET3.

The examiner also rejected claims 26 and 28 under 35 U.S.C. § 112, second paragraph, as being indefinite in the recitation of the phrase "function of a stabilizing protein" (claim 26) as well as the phrase "function of a replication protein" (claim 26 and 28). The applicants believe these phrases add nothing to the patentabilty of the claim and thereby have amended claims 26 and 28. Claim 26 is now directed to an isolated DNA sequence encoding at least one protein selected from the group consisting of a protein comprising the amino acid sequence of SEQ ID NO: 2 and a protein comprising the amino acid sequence of SEQ ID NO: 3. Claim 28 is now directed to an isolated DNA sequence encoding a protein comprising the amino acid sequence of SEQ ID NO: 5.

Finally, the examiner rejected claim 22 under §112, second paragraph, for assertedly being indefinite for lacking antecedent basis for the plasmid in claim 30 since claim 30 is directed to an isolated DNA instead of a plasmid. The applicants have amended claim 22 to

be dependent upon claim 21 which is directed to the pTET3 plasmid and therefore has sufficient antecedent basis.

In view of the foregoing amendments and remarks, the rejection of claims 2, 3, 5, 13, 15, 16, 22, 26, and 28 under 35 U.S.C. § 112, second paragraph, has been overcome and should be withdrawn.

Rejection Pursuant to 35 U.S.C. § 112, first paragraph, Written Description

On page 5 of the official action, the examiner rejected claims 2-6 under 35 U.S.C. § 112, first paragraph, for lacking written description. Specifically, the examiner alleged that both parts i) and ii) of pending claim 2 lack any structure, but the DNA replication region obtained from plasmids pTET3 or pCRY4 were sufficiently described in Figures 3 and 4.

Solely for the purpose of expediting prosecution, and without prejudice to the applicants' right to seek broader claims in a continuing application, the applicants have cancelled claims 3-5 without prejudice, thereby obviating the rejection of these claims. As discussed above, amended claim 2 is directed to a plasmid capable of autonomous replication in bacteria of the genus Corynebacterium, said plasmid comprising (i) at least one region that encodes a protein involved in a biosynthetic pathway selected from the group consisting of L-lysine and pantothenic acid; (ii) at least one DNA replication region obtained from one of the plasmids pTET3 or pCRY4, and (iii) at least one region that encodes a protein for active antibiotic resistance comprising a gene selected from the group consisting of a gene encoding a protein conferring tetracycline resistance, a gene encoding a protein conferring streptomycin and spectinomycin resistance, and a gene conferring sulfamethoxazole resistance, wherein said genes are obtained from the antibiotic resistance region of plasmid pTET3, as set forth in Figure 5. Amended claim 6 is directed to a plasmid capable of autonomous replication in bacteria of the genus Corynebacterium containing at least one DNA replication region obtained from one of the plasmids pGA1, pGA2, pTET3, or pCRY4, and at least one region encodes for a protein for active antibiotic resistance comprising a gene selected from the group consisting of a gene encoding a protein conferring tetracycline resistance, a gene encoding a protein conferring streptomycin and spectinomycin resistance, and a gene conferring sulfamethoxazole resistance, wherein said genes are obtained from the antibiotic resistance region of plasmid pTET3, as set forth in Figure 5.

The applicants hereby submit each component of the plasmids of claims 2 and 6 are fully supported and described in the specification. With regard to claims 2 and 6, the antibiotic resistance genes of the antibiotic region of pTET3 are described page 30, lines 14-33 and figure 5. With regard to claim 2, the region that encodes a protein involved in a biosynthetic pathway selected from the group consisting of L-lysine and pantothenic acid is described on page 13, line 29 to page 14, line 7 and Examples 11 and 12. In view of the foregoing amendments and remarks, the applicants submit that the rejection of claims 2 and 6 pursuant to 35 U.S.C. § 112, first paragraph, for lack of written description has been overcome, and the rejection of claims 3-5 is moot. Accordingly, the applicants request withdrawal of the rejection.

Rejection Pursuant to 35 U.S.C. § 112, First Paragraph, Enablement

On pages 6 and 7 of the official action, the examiner rejected claims 2, 3, 5, 6, 13-16, 18, and 21-25 under 35 U.S.C. § 112, first paragraph, for lacking enablement. Specifically, the examiner alleged that the applicants filing of a declaration stating the referred plasmids have been deposited under the terms of the Budapest Treaty is not persuasive with respect to plasmid pCRY4 because the declaration does not refer to the plasmid pCRY4, but rather pCRY4m. With regard to claims 22 and 25, the examiner alleged that plasmids pGA3, pBL1 and pHM1519 is not disclosed by the specification to obtain the plasmids in a repeatable process and it is not apparent if the DNA sequences are readily available to the public.

Solely for the purpose of expediting prosecution, and without prejudice to the applicants' right to seek broader claims in a continuing application, the applicants have cancelled claims 3-5, 13, and 14 thereby rendering moot the rejection as applied to each of these claims. The applicants submit herewith a declaration by the undersigned stating that pCRY4 has been deposited under the Budapest Treaty as DSM Accession No. 5816, deposited on February 23, 1990 at the Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSM), Mascheroder Weg 1B, D-3300 Braunschweig, Germany.

Claim 22 is now directed to an isolated plasmid pTET3 of claim 21, wherein said plasmid is compatible with one or more plasmids selected from the group consisting of pGA1, pGA2, pAG3, pBL1, and pHM1519. Clam 25 is now directed to an isolated plasmid pCRY4 of claim 24, wherein said plasmid is compatible with one or more of the plasmids selected from the group consisting of pGA1, pGA2, pAG3, pBL1, and pHM1519. The applicants submit that plasmids pGA1, pGA2, pAG3, pBL1, and pHM1519 are readily

available and described to the public as taught in the specification on page 2, lines 6-22 and page 14, line 25 to page 15, line 7. Specifically, pHM1519 has been deposited by Miwa *et al., Agricultural and Biological Chemistry* 48:2901-2903 (1984) in *Corynebacterium glutamicum* ATCC13058 (see page 2, lines 16 and 17). Plasmid pBL1 has been deposited by Santamaria *et al., J. of Gen. Microb.* 130:2237-2246 (1987) in *Brevibacterium lactofermentum* ATCC21798 (see page 2, line 12). Plasmids pGA1 and pGA2 in addition to plasmids pTET3 and pCRY4 have been deposited in *Corynebacterium glutamicum* LP-6 DSM5816 (see EP 0 472 869) (see page 5, lines 25-30) according to the Budapest Treaty. Plasmid pAG3 has been isolated from Corynebacterium melassecola 22220 and described in U.S. Patent Number 5,158,891 (see page In addition, the specification discusses the availability of pGA1, pBL1, and pHM1519 on page 14, lines 14-20.

Accordingly, the applicants submit that the rejection of claims 2, 3, 5, 6, 13-16, 18, and 21-25 under 35 U.S.C. § 112, first paragraph, for lacking enablement has been overcome and should be withdrawn.

III. CONCLUSION

In view of the foregoing, the claims are now believed to be in form for allowance, and such action is hereby solicited. If any point remains in issue which the examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number listed below.

All objections and rejections have been addressed, it is respectfully submitted that the present application is in a condition for allowance and a notice to that effect is earnestly solicited.

By 

Thomas A. Cawley, Jr., Ph.D.
Reg. No. 40,944
Attorney for Applicants

TAC/PAJ
Pillsbury Winthrop LLP
1600 Tysons Boulevard
McLean, VA 22102
Tel.: 703.905.2144
Fax.: 703.905-2500